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# **VACCINE SAFETY**

# **CDC Media Availability on Vaccine Safety**

On March 6, CDC held a <u>press telebriefing</u> to outline the public health response to childhood vaccine safety. The call was intended to answer some of questions and misstatements that have arisen in the media in response to a recent vaccine injury compensation case. As discussion of individual claims filed under the Childhood Vaccine Injury Act is prohibited without the written consent of the person who submitted the information, the experts on the call did not discuss specifics of the case, but rather provided general information on related terms and concepts, especially mitochondrial diseases and disorders. Speakers included Dr. Julie Gerberding, director, CDC; Dr. Tom Insel, director, National Institute of Mental Health, National Institutes of Health; and Dr. Bruce Gellin, director, National Vaccine Program Office, Department of Health and Human Services. An archived <u>Webcast</u> as well as <u>transcript</u> of the event are available.

On March 3, the Health Resources and Services Administration gave a <u>statement</u> on autism and the Vaccine Injury Program. Further information is available on the <u>National Vaccine Injury Compensation Program</u>, the <u>U.S. Court of Federal Claims</u> - Office of Special Masters, and the <u>Guidance for Practice under VICP</u>.

### For more information

- CDC Vaccine Safety Website (new!)
- CDC Autism Information Center
- Facts about Mitochondrial Disease (CDC)

# **COMMUNICATING ABOUT VACCINE SAFETY**

## **Talking to Parents about Autism**

Reprinted with permission from the January/February 2008 issue of For Your Child's Health, Children's Hospital of Philadelphia

Yes to genetics, no to vaccines link. It is not completely understood what causes autism, whose symptoms include difficulty in social interaction and communication. New evidence, however, points to genetics in some cases. Scientists have uncovered a new gene linked to the disorder that may predispose children to autism. They've also found an association between loss of a portion of a gene, chromosome 16, and autism.

A possible connection between mercury in childhood vaccines and autism also has had many parents worried. Now researchers say a new study should help reassure moms and dads. The researchers found that five years after the removal of thimerosal, a mercury-rich vaccine preservative, autism diagnosis

rates are still climbing. Although the rate of autism increased during the years 1995 to 2007, the preservative has not been used in childhood vaccines since 2001. While it's not known why autism diagnosis is rising, a broader classification of autism may account for the increase.

### For more information

- Children's Hospital of Philadelphia
- MMR vaccine does not cause autism

# **Risk Communication Tips**

Reprinted from the National Immunization Coalitions Technical Assistance Network's online newsletter, the IZ TA Update (Vol. 2, Issue 13, July 19, 2006)

How you communicate information to your target audience is very important in any campaign – especially public health campaigns. Accurately relaying facts and conveying the benefits and risks associated with immunization is essential; miscommunication can severely undermine your efforts, resulting in fewer vaccinations because people have fallen prey to false rumors.

To effectively communicate vaccine risk:

- Provide risk comparisons: For example, what will happen to a person if he/she does not get a flu shot? Hospitalization? Death? In the words of risk communication expert Peter Sandman, "...vaccination isn't just a risk. It is a precaution aimed at mitigating a greater risk." Give your audience enough information so that they can evaluate which of two or more options is riskier, such as, getting a little soreness or swelling at the site where the shot is given...or possibly being one of the approximately 200,000 people who are hospitalized every year due to complications from influenza?
- State the facts: Present the facts clearly, truthfully, and succinctly. Don't sugarcoat information; likewise don't use scare tactics or paint a picture of gloom and doom. Concealing important information or hiding facts can be detrimental to gaining the trust of your audience.
- Provide rationale for advice: Why is it important for members of your target audience to take an action to do something? What's the benefit to them? Will the action help them stay healthy for themselves and their families?
- Provide an action statement: What should the recipient of your message do upon hearing your message? Call the doctor? Take their 9 month old infant to get a flu shot? Articulate a clear call to action.

Keeping these tips in mind while crafting your messages will help you to communicate about the risks associated with various vaccines in an effective, reassuring, and productive manner.

# **WHAT'S NEW**

#### **ACIP Revises MMRV Recommendations**

After new information was presented on the risk of febrile seizures after measles, mumps, rubella, and varicella (MMRV) vaccine, the ACIP updated recommendations to remove its previous preference for administering combination MMRV vaccine over separate injections of measles, mumps, and rubella (MMR) vaccine and varicella vaccine. The updated recommendations have been published in CDC's Morbidity and Mortality Weekly Report (MMWR). This safety update provides information for health care providers about the risk of febrile seizures after MMRV vaccine, ongoing CDC and FDA MMRV vaccine safety activities, and clinical guidance for use of MMRV vaccine.

### For more information

- MMRV Package Insert (revised 2/27/2008)
- What Clinicians Need to Know about MMRV Vaccine Safety
- 2008 Child and Immunization Schedules

## MMR and Varicella Vaccine Information Statements (VIS) are Updated

Since the ACIP updated the recommendations for the use of MMRV, it was also necessary to update the Vaccine Information Statements (VIS) for both the MMR and varicella vaccines. When giving MMRV, the new VIS should be used. When giving MMR or varicella vaccine separately, the previously-published VIS may be used until stocks are depleted. Aside from two boxes containing information about MMRV, both VIS are identical to the previous editions.

The new VIS are posted on the MDCH Division of Immunization website.

### CDC Publishes a New Multi-Vaccine VIS

On January 30, CDC published a <u>new multi-vaccine VIS</u>. After receiving numerous questions from providers about the appropriate use of the new Vaccine Information Statement (VIS), the Division of Immunization created a handout on the Use of the Multi-Vaccine VIS.

CDC also posted a FAQ document on the multi-vaccine VIS on its website.

## Meningococcal VIS also Updated

The meningococcal VIS was updated to incorporate the licensure of MCV for 2-10 year olds. The new edition is dated 1/28/08. Existing stocks of the last version can be used up, although the new version should be used when administering MCV to anyone in the 2-10 age group. The updated meningococcal VIS is posted on the MDCH website. Please note that the updated VIS is still an interim version.

# The Vaccine Information Statements are Customized for Use in Michigan

In Michigan, it is important that vaccine recipients, their parents, or their legal representatives be given the Michigan versions of VIS because they include information about the Michigan Care Improvement Registry (MCIR). By state law in Michigan, parents must be informed about MCIR. Vaccine Information Statements that are obtained from other sources (e.g., from the CDC or IAC websites) do not contain information about MCIR.

#### For more information

- Instructions for the Use of Vaccine Information Statements
- Important Vaccine Information Statement (VIS) Facts

# **EVENTS**

# Adolescent Immunization Conference will be held June 5<sup>th</sup>

## William Atkinson, M.D., M.P.H., will be the keynote speaker

The Michigan Department of Community Health Division of Immunization is pleased to announce an Adolescent Immunization Conference to be held on June 5. William Atkinson, M.D., M.P.H., of the Centers of Disease Control and Prevention (CDC) will provide the keynote address. The purpose of the Adolescent Immunization Conference is to:

- Promote adolescent immunizations in Michigan
- Educate providers about newly recommended adolescent vaccines
- Overcome barriers to vaccinating adolescents
- Discuss strategies for increasing adolescent immunization rates
- Give providers the tools to communicate with parents, pre-teens, teens, and adolescents through college age about the importance of vaccination

Date & Time: Thursday, June 5, from 8:30 a.m. to 4:00 p.m.

Registration Fee: \$50.00

Place: Grand Valley State University, Eberhard Center, Grand Rapids

A conference agenda and registration website will be distributed in April and CME credits will be available. Information will also be posted on the conference registration website.

For more information, please contact Courtnay McFeters, M.A., at McFetersc@michigan.gov.

## Fall Regional Immunization Conferences Scheduled in October & November

The Michigan Department of Community Health (MDCH) will once again offer eight regional immunization conferences in October and November. The one-day fall conferences have annually attracted a large number of health care professionals who attend to learn about practice-management tools, techniques and information that will help ensure that patients throughout the state are fully immunized.

If you received this newsletter through email, you will automatically receive the conference brochure. Conference brochures will be distributed during the first week of August.

If you have any colleagues who did not receive this newsletter via email, please share it with them, and encourage them to sign up to receive this newsletter directly from the listsery.

**How to subscribe** (not applicable to those who are already subscribers)

- 1. Send an email message to <u>franklinr@michigan.gov</u> and enter the word SUBSCRIBE in the SUBJECT field.
- 2. That's all, you're done!

Once you've sent the email, you will be added to the Immunization Listserv Group. You will receive the Fall Regional Immunization Conferences brochure, further details about the Adolescent Immunization Conference discussed on page 5, and this newsletter. Beginning this year, conference brochures will be distributed solely through email. Information about all of our conferences will also be posted on the MDCH website at <a href="https://www.michigan.gov/immunize">www.michigan.gov/immunize</a> (under the Provider Information section).

Again, if you received this newsletter by email, you do not need to subscribe again. All of the people who receive the newsletter by email will also receive information about any conferences that are being held by the MDCH Division of Immunization (the same lists are used for both of these purposes).

Once you have received your conference brochure, we encourage you to register early since space is limited. (However, registrations will not be accepted before August 1.)

## **Fall Regional Immunization Conferences Schedule**

October 14 – Gaylord	October 30 – Ypsilanti
October 16 – Marquette	November 12 – Troy
October 28 – Kalamazoo	November 13 – Detroit
October 29 – Kalamazoo	November 20 – East Lansing

Registration will begin August 1; please note that registrations will not be accepted prior to that date.

For more information, go to www.michigan.gov/immunize (under the Provider Information section).

If you have any questions, please email Rosemary Franklin at franklin@michigan.gov.

# **HPV Schedule Updated**

There is a correction to the HPV vaccine regimen in the <u>Catch-up Immunization Schedule</u>. The entry to HPV vaccine was changed to:

- Dose 1 to 2: 4 weeks
- Dose 2 to 3: 12 weeks (and 24 weeks after the first dose)

This means that the third dose needs to be administered no earlier than 6 months from the first dose. The minimum intervals between dose one and dose two as well as between dose two and dose three remain unchanged. An MMWR erratum to reflect this change is in the process.

# **QUESTIONS & ANSWERS**

Question: How can I explain to parents why we should give Gardasil to preteens/young teens?

**Answer:** 

HPV is a very common sexually transmitted infection. More than half of sexually active people will be infected with HPV in their lifetime. HPV vaccine protects against 4 types of HPV. Girls should receive this vaccine before their first sexual contact when they can be exposed to HPV. This is because the vaccine prevents disease in girls who have not previously gotten one or more types of HPV prevented by the vaccine. It does not work as well for those who were exposed to the virus before getting the vaccine.

CDC has developed <u>education materials</u> about immunizations that adolescents should receive. These include informational sheets and posters about HPV vaccine as well as other vaccines needed at this time. Tetanus, diphtheria, pertussis (Tdap), and meningococcal vaccine (MCV4) are also routinely recommended for this age group. These <u>materials for both pre-teens</u> and adolescents are available free on the CDC website.

If you have any additional questions, please contact your local health department or the MDCH Division of Immunization at 517-335-8159.

Question: If a woman turns 27 years of age after the first dose of HPV was administered but before the third doses is administered, should the series be completed?

Yes, the series should be completed using the recommended intervals between doses, even if this means that the series is completed after a woman turns 27 years of age.

For more information:

Answer:

■ <u>HPV Vaccine</u> – <u>More Que</u>stions & Answers

# **INFLUENZA**

# **Influenza Vaccine Recommendations Expand**

During its February meeting, ACIP voted to expand the recommended ages for annual influenza vaccination of children to include all children from 6 months through 18 years of age. (The previous recommendation was for vaccination of children from 6 months to 59 months of age.) The expanded recommendation is to take effect as soon as feasible, but no later than the 2009–2010 influenza Season. It increases the number of children recommended for vaccination by approximately 30 million. Studies have shown that healthy children bear a significant burden from influenza disease and are at increased risk of needing influenza-related medical care. In addition, there is evidence showing that reducing influenza transmission among children has the potential to reduce influenza among their household contacts and within the community. This change is expected to be reflected in the 2009 child and adolescent schedules, after publication in CDC's *Morbidity and Mortality Weekly Report* (MMWR). More information can be found in the CDC Press Release on this topic.

#### **Influenza Vaccine Effectiveness**

Surveillance information indicates that H3N2 viruses are currently the viruses that are circulating most widely in the U.S., and the majority of these are not optimally matched to the strains represented in the vaccine. Influenza viruses are constantly changing so it's common for new strains of influenza viruses to appear each year. The effectiveness of the vaccine depends in part on the match between the viruses in the vaccine and influenza viruses that are circulating in the community. If these are closely matched, vaccine effectiveness is higher. If they are not closely matched, vaccine effectiveness can be reduced. However, even when the viruses are not closely matched, the vaccine can still protect many people and prevent flu-related complications. Such protection is possible because antibodies made in response to the vaccine can provide some protection (called cross-protection) against different, but related strains of influenza viruses. Vaccination remains the best method for preventing influenza and its potentially severe complications in children and adults even in years where there is a suboptimal match between vaccine and circulating strains of influenza viruses. CDC will continue to study this season's vaccine's effectiveness and will make more information available in the coming weeks. For more information about the effectiveness of seasonal influenza vaccine, CDC has posted an FAQ on its website called How Well Does the Seasonal Flu Vaccine Work?

#### FDA Selects Influenza Virus Strains for U.S. 2008-09 Vaccine

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met in Gaithersburg, Maryland, on February 21, 2008, to <u>select the influenza virus strains</u> for the composition of the influenza vaccine for use in the 2008-09 U.S. influenza season. During this meeting, the advisory panel reviewed and evaluated the surveillance data related to epidemiology and antigenic characteristics, serological responses to 2007-08 vaccines, and the availability of candidate strains and reagents.

The panel recommended that vaccines to be used in the 2008-2009 influenza season in the U.S. contain the following:

- an A/Brisbane/59/2007 (H1N1)-like virus;
- an A/Brisbane/10/2007 (H3N2)-like virus; \*
- a B/Florida/4/2006-like virus. #
- \* A/Brisbane/10/2007 is a current southern hemisphere vaccine virus.
- # B/Florida/4/2006 and B/Brisbane/3/2007 (a B/Florida/4/2006-like virus) are current southern hemisphere vaccine viruses.

The influenza vaccine composition to be used in the 2008-09 influenza season in the U.S. is identical to that recommended by the <u>World Health Organization</u> on February 14, 2008, for the Northern Hemisphere's 2008-09 influenza season.

## Flu Fighter Action Kit Now Posted Online

Recommendations for Health Care Personnel (HCP) to get an annual flu vaccine have been in place since 1981. Despite these recommendations, three out of five HCP put themselves, their families, and their patients at risk by not being vaccinated against the flu.

Reducing influenza transmission from HCP to patients has become a top priority in Michigan. Vaccination of HCP has been associated with reduced work absenteeism and fewer deaths among nursing home and elderly hospitalized patients.

The Michigan Department of Community Health Flu Education Workgroup, along with partners from the Michigan Flu Advisory Board, Michigan Advisory Committee on Immunization, and Alliance for Immunization in Michigan has developed a Flu Fighter Action Kit to serve as a framework for implementing an immunization program in a health care facility, geared at immunizing HCP against influenza. Information in this kit can be modified to develop an immunization program for all HCP vaccinations.

Become a Flu Fighter. Protect yourself, your colleagues, and your patients.

To view the online Flu Fighter Action Kit visit www.michigan.gov/flufighterkit.

## More Nursing Home Employees Protected against Flu

In 2004, the majority (63%) of nursing homes reported less than 60% employees had received an influenza shot during the last influenza season. In 2004, nursing homes used different strategies to promote influenza vaccination among employees. Three of these strategies (offering free vaccinations, furloughing employees with influenza-like illness, and requiring proof of vaccination) were significantly associated with staff influenza vaccination rates increasing to 60%. Only 1% of surveyed facilities did not use at least one of the strategies. Data from the 2004 National Nursing Home Survey can be found in CDC's Morbidity and Mortality Weekly Report under "QuickStats."

## Michigan Flu Surveillance & FluBytes Newsletters are Posted Online

The MI FluFocus surveillance report and the FluBytes newsletter are published every Friday and then posted on the MDCH website. Be sure to check both publications frequently, in order to obtain the most accurate and up-to-date seasonal influenza information. Information about influenza activity in the U.S. is posted on the CDC website.

## Families Fighting Flu has Published an Online Newsletter

<u>Families Fighting Flu (FFF)</u>, an organization made up of parents whose children died or who became seriously ill from influenza, has recently established an e-newsletter called Fighting Flu. The e-newsletter contains information about FFF activities, personal stories, and influenza educational materials. It can be downloaded from the home page of FFF's website.

# **VACCINE SHORTAGES**

## **Hepatitis A Vaccine Delays**

Merck & Co., Inc. are experiencing production delays for Pediatric and Adult hepatitis A vaccine (Pediatric & Adult VAQTA®). Merck has temporarily discontinued accepting orders for Pediatric VAQTA® and Adult VAQTA® in the vial formulation. Based on current information, it is estimated that VAQTA® will be available in early third quarter 2008 and Adult VAQTA® in fourth quarter 2008. GSK production and supply of their Pediatric and Adult hepatitis A vaccine (Pediatric & Adult Havrix®) and their Adult hepatitis A/hepatitis B combination vaccine (Twinrix®) are currently in good supply to meet demand. GSK has initiated plans to increase production of Havrix® and Twinrix®, to help ensure uninterrupted supply for the U.S. market. Further updates on vaccine shortages and delays can be found on CDC's Current Vaccine Shortages & Delays Website.

## **Hib Shortage Flyer now Available**

CDC recently posted a <u>Hib Vaccine Shortage flyer</u> on its website. The document shows who should and who shouldn't receive Hib vaccine at this time, and is designed to be posted in your clinic.

### Are you receiving automatic email updates directly from CDC?

To receive email updates on vaccine shortages and delays automatically, go to: <a href="https://www.cdc.gov/vaccines/vac-gen/shortages">www.cdc.gov/vaccines/vac-gen/shortages</a>. Double-click on the picture of the mailbox shown in the center of the page. Email updates on vaccine shortages and delays will be sent to you automatically.

To receive a free electronic subscription to MMWR (which includes new ACIP statements), go to: http://www.cdc.gov/mmwr/mmwrsubscribe.html.

# **RESOURCES**

# Immunization Listserv Group is Kept in the Loop

If you received this newsletter from <a href="michiganimmunization@msmsnet.msms.org">michiganimmunization@msmsnet.msms.org</a>, then you're already part of the Immunization Listserv Group. So far this year, the Division of Immunization has used the Immunization Listserv Group more than ever. During the past few months, the subject of vaccine safety has been in the news frequently. CDC has been very effective at providing the states with notices about upcoming news events, talking points to assist providers and public officials in answering questions, and numerous resources on vaccines and vaccine safety. When the Michigan Department of Community Health receives these messages from CDC, we disseminate them to our immunization partners through email without delay.

When vaccines and vaccine safety are in the news, you can expect to receive more emails from our Division. We will take care to not bombard you with frivolous email messages; however, I think we can all agree that this type of information is certainly not frivolous.

If you have any colleagues who are not on the Immunization Listserv Group yet, please share this newsletter with them. Any readers who did not receive this newsletter directly from the listserv are encouraged to have their email addresses added to the group.

**How to subscribe** (applicable only to those who are not already subscribers)

- 3. Send an email message to <u>franklinr@michigan.gov</u> and enter the word SUBSCRIBE in the SUBJECT field.
- 4. That's all, you're done!

Once you've sent the email, you will be added to the Immunization Listserv Group. You will receive this newsletter periodically, as well as the types of email messages that are described above. In addition, you will receive information about the June 5<sup>th</sup> Adolescent Immunization Conference and the Michigan Department of Community Health Fall Regional Immunization Conferences.

If you have any questions or comments, please contact Rosemary Franklin at <u>franklinr@michigan.gov</u> or 517-335-9485.

## **Epidemiology and Prevention of Vaccine-Preventable Diseases**

This four-part series is no longer being delivered via satellite or live webcast. The 2008 series will be available on DVD and Web-on-Demand in May. Continuing Education credit will be available for each individual 3-hour session. Information about <u>distribution of DVDs and other details about the course</u> will be posted on the CDC website.

The book that accompanies this course shares the same name as the course itself, the Epidemiology and Prevention of Vaccine-Preventable Diseases. The Pink Book, as it is also called, is scheduled to be released in April. This will be the 10th Edition, 2nd Printing. The Public Health Foundation is taking orders at this time.

The easy-to-reference Pink Book contains comprehensive information on each vaccine-preventable disease, as well as information on principles of vaccination, general recommendations on immunization, immunization strategies for healthcare practices and providers, and vaccine safety.

The price is \$35.00 plus shipping fees. Order your copy by calling toll free 877-252-1200 and asking for item no. RM-053B. Purchase orders/checks should be mailed/faxed to Public Health Foundation, PHF Publications Sales, PO Box 753, Waldorf, MD 20604-0753, (301) 843-0159 (fax). You can also purchase the Pink Book online at the Public Health Foundation Bookstore.

#### **More Resources**

## New Spanish Adult Immunization Schedule

A new, <u>Spanish-Language Version</u>, <u>2007-2008 Recommended Adult Immunization Schedule</u> is now available. The schedule was released in English in October 2007.

- Alliance for Immunization in Michigan (AIM) Online Provider Toolkit Updated for 2008!
  www.aimtoolkit.org
- The Vaccine Education Center at the Children's Hospital of Philadelphia

The Vaccine Education Center has developed many materials which are available mostly free-of-charge to healthcare providers throughout the country and the world. These materials address specific vaccines and issues such as vaccine safety. Available materials include informational tear pads, videos, bookmarks and booklets as well as two Web sites. There is also a monthly email newsletter for the public, called Parents PACK (Possessing, Accessing and Communicating Knowledge about vaccines). For more information, please visit <a href="http://vaccine.chop.edu">http://vaccine.chop.edu</a> and <a href="http://vaccine.chop.edu/parents">http://vaccine.chop.edu/parents</a>.

### ACIP-VFC Vaccine Resolutions

Sign up to receive automatic email updates at <a href="www.cdc.gov/vaccines/programs/vfc/acip-vfc-resolutions.htm">www.cdc.gov/vaccines/programs/vfc/acip-vfc-resolutions.htm</a>. When the website opens up, double-click on the picture of the mailbox shown in the center of the web page (it says "get email updates"). After following the simple instructions that follow, email updates will be sent to you automatically as soon as they are available.

# Vaccine Management Recommendations

<u>Vaccine Management Recommendations for Storage and Handling of Selected Biologicals</u> is now posted on the CDC website.

### Status of Licensure of New Vaccines

Check the Red Book Online regularly to stay current on which vaccines are licensed or waiting to be licensed at http://aapredbook.aappublications.org/news/vaccstatus.shtml.

# The Michigan Immunization Update newsletter

- The <u>Michigan Immunization Update newsletter</u> is distributed electronically through an immunization listsery. The current issue and past issues are posted on the Michigan Department of Community Health website at <u>www.michigan.gov/immunize</u> under the Provider Information section.
- Share your photos and stories with us! Please email your photos, stories, story ideas, and suggestions and comments to Rosemary Franklin.
- **Contact information:** Rosemary Franklin can be contacted at <u>franklinr@michigan.gov</u> or 517-335-9485.